

Docket No.: 4614-0160PUS1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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In re Patent Application of:  
Marc DONATH

Application No.: NEW

Confirmation No.: N/A

Filed: December 9, 2004

Art Unit: N/A

For: USE OF AN INTERLEUKIN 1 RECEPTOR  
ANTAGONIST AND/OR  
PYRROLIDINEDITHIOCARBAMATE FOR  
THE TREATMENT OR PROPHYLAXIS OF  
TYPE 2 DIABETES

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Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT (IDS)**

MS PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

This Information Disclosure Statement accompanies the new patent application submitted herewith.

Copies of the references on the PTO/SB/08 are not provided.

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Those documents which are marked with a double asterisk (\*\*) next to the Cite No. in the attached form PTO/SB/08 (facsimile) are not supplied because they were previously cited by or submitted to the Office in a prior application number PCT/JP2003/006682, filed June 25, 2003.

A concise explanation of relevance of the items listed on form PTO/SB/08 is in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 02-2448, under Order No. 4614-0160PUS1. A duplicate copy of this paper is enclosed.

Dated: December 9, 2004  
LRS/CAM/nl

Respectfully submitted,

By  #d2.874

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DT05 Rec'd PCT/PTO 09 DEC 2004

PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449A/B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	NEW
				Filing Date	December 9, 2004
				First Named Inventor	Marc DONATH
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	1	Attorney Docket Number	4614-0160PUS1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)					
	BA	EP-1 018 514-A		07-12-2000			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T <sup>2</sup>
	CA**	Dinarelli et al., "Blocking IL-1: interleukin 1 receptor antagonist in vivo and in vitro", Immunology Today, Vol. 12, No. 11, 1991, pages 404-410.			
	CB**	Mandrup-Poulsen et al., "Involvement of interleukin 1 and interleukin 1 antagonist in pancreatic and beta-cell destruction in insulin-dependent diabetes mellitus", Cytokine, Vol. 5, No. 3, 1993, pages 185-191.			
	CC**	Meier et al., "IL-1 receptor antagonist serum levels are increased in human obesity: a possible link to the resistance to leptin?", Journal of Clinical Endocrinology & Metabolism, Vol. 87, No. 3, 2002, pages 1184-1188.			
	CD**	Donath et al., "Hyperglycemia-induced beta-cell apoptosis in pancreatic islets of Psammomys obesus during development of diabetes", Diabetes, Vol. 48, No. 4, 1999, pages 738-744.			
	CE**	Bedoya et al., "Pyrrolidine dithiocarbamate prevents IL-1-induced nitric oxide synthase mRNA, but not superoxide dismutase mRNA, in insulin producing cells", Biochemical and Biophysical Research Communications, Academic Press Inc., Florida, Vol. 210, No. 3, 1995, pages 816-822.			
	CF**	Yamamoto et al., "Role of the NF-kappaB pathway in the pathogenesis of human disease states", Current Molecular Medicine, Bentham Science Publishers, Great Britain, Vol. 1, No. 3, 2001, pages 287-296.			
	CG**	Flodstrom et al., "Cytokines activate the nuclear factor KAPPAB (NF-KAPPAB) and inducible nitric oxide production in human pancreatic islets", FEBS Letters, Elsevier Science Publishers, The Netherlands, Vol. 385, No. 1/2, 1996, pages 4-6.			
	CH**	Maedler et al., "Glucose-induced beta cell production of IL-1beta contributes to glucotoxicity in human pancreatic islets", Journal of Clinical Investigation, Vol. 110, No. 6, 2002, pages 851-860.			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. \*\* CITE NO.: Those document(s) which are marked with an double asterisk (\*\*) next to the Cite No. are not supplied because they were previously cited by or submitted to the Office in a prior application relied upon in this application for an earlier filing date under 35 U.S.C. 120.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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